

A2 4. (Amended) Sustained-release pharmaceutical formulation according to [any one of Claims 1 to 3] Claim 1, wherein [characterized in that] the organic acid is selected [chosen] from the group consisting of maleic, tartaric, malic, fumaric, lactic, citric, adipic and succinic acid [acids] in the form of a racemate [racemates] or an isomer [isomers].

Claim 5, line 2, change "any one of Claims 1 to 4" to
--Claim 1--;
line 3, change "characterized in that" to
--wherein--.

Claim 6, line 2, change "characterized in that" to
--wherein--.

Claim 7, lines 1-2, change "any one of Claims 1 to 6" to
--Claim 1--;
line 2, change "characterized in that" to
--wherein the formulation--.

Add the following new claims:

A2 8. Coated sustained release tablet containing mizolastine, comprising a sustained-release tablet containing mizolastine, a fatty matrix and an organic acid, the coated tablet having a dissolution profile which is pH independent.

9. The tablet of claim 8, wherein the dissolution profile is one in which about 30 to 70% of the mizolastine is dissolved in 1 hour and 100% of the mizolastine is dissolved in 3 to 5 hours.

10. The tablet of Claim 8, wherein the weight ratio between the mizolastine and the organic acid is between 0.3 and 1.

11. The tablet of Claim 8, wherein the fatty matrix is selected from the group consisting of hydrogenated castor oil, a hydrogenated lecithin, a long-chain fatty acid and a triglyceride esterified with one, two or three medium-chain fatty acids.

12. The tablet of Claim 8, wherein the organic acid is selected from the group consisting of maleic, tartaric, malic, fumaric, lactic, citric, adipic and succinic acid in the form of a racemate or an isomer.

13. The tablet of Claim 8, wherein the organic acid is L-tartaric acid.

14. The tablet of Claim 13, wherein the ratio between the mizolastine and the L-tartaric acid is 0.5.

15. The tablet of Claim 8, wherein the formulation contains from 1 to 25 mg of mizolastine.

16. The tablet of Claim 8, wherein the organic acid has a pK of 2 or more.

17. Coated sustained-release tablet containing mizolastine, comprising a sustained-release tablet containing from 1 to 25 mg of mizolastine, a fatty matrix and an organic acid having a pK of 2 or more, the weight ratio between the mizolastine and the organic acid is between 0.3 and 1, the organic acid is L-tartaric acid.

18. The tablet of Claim 11, wherein the ratio between the mizolastine and the L-tartaric acid is 0.5

19. The tablet of Claim 18, wherein the fatty matrix is hydrogenated castor oil.

20. The tablet of Claim 19, wherein the tablet has a dissolution profile which is independent of pH and is one in which about 50% of the mizolastine is dissolved in 1 hour and 100% of the mizolastine is dissolved in 3 to 5 hours.

21. Coated sustained release tablet, consisting essentially of mizolastine, a fatty matrix, an organic acid and a coating.

22. Coated sustained release tablet, consisting essentially of mizolastine, a fatty matrix, an organic acid, and a coating, the coated tablet having a dissolution profile which is pH independent.

23. Coated sustained release tablet, consisting essentially of mizolastine, a fatty matrix, an organic acid, and a coating, the coated tablet having a dissolution profile which is pH independent, the organic acid being selected from the group consisting of maleic, tartaric, malic, fumaric, lactic, citric, adipic and succinic acid in the form of a racemate or an isomer.--

R E M A R K S

The present continuation is directed to cancelled claims 1-23 of the parent application.